REMARKS

The applicant respectfully requests reconsideration of claims 35-53, 56-60, 64-68 and 71-79 in view of the foregoing amendment, and consideration of new claims 80-86. The acceptance of the previously filed terminal disclaimers, and indication that claims 42-43, 46, 49-50, 52, 66 and 76-79 incorporate allowable subject matter, are noted and appreciated.

A. Claims 35-38, 44, 45, 47-48, 56-60, 65 and 68 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 5,443,500 (Sigwart).

The Sigwart patent discloses an intravascular stent, preferably of the balloon-expandable type. The stent consists of a flat rectangular sheet of biocompatible, malleable material (column 3, lines 6-7), e.g. stainless steel (column 1, line 28). The stent is held in a "rolled-up state" by a holding wire 8 laced through at least two layers of the spiral formed by the stent. The wire can be removed by pulling from the outside (column 3, lines 30-35).

In use, the stent is radially expanded by inflating a balloon, after pulling out the holding wire (column 3, lines 38-39). As an alternative, the stent can be radially self-expandable (column 4, lines 55-58).

Claim 35 is amended to define the marker as removably attached to the endoprosthesis to improve a radiopacity of the endoprosthesis, with the marker being removable from the endoprosthesis when the endoprosthesis is *in vivo*.

As noted in the present specification, retrievable radiopaque markers can improve radiopacity and the locatability of endoprostheses in various medical procedures. See the specification at page 2, lines 18-20. Use of a retrievable or removably attached radiopaque marker on an implantable endoprosthesis is advantageous because the radiopaque property may be present only for the desired time period (page 3, lines 10-12). Thus, endoprostheses formed of polymers and other generally radiolucent materials can be successfully positioned through fluoroscopic imaging.

In the present rejection, it is asserted that Sigwart discloses an implantable endoprosthesis and a radiopaque marker system (Action, page 3).

This assertion is respectfully traversed. Sigwart does not discuss fluoroscopic imaging, and does not distinguish the materials of its stent or holding wire as to their radiopacity.

Sigwart's holding wire 8 has nothing to do with improving the radiopacity of the stent (rolled sheet 1). The only purpose disclosed for the holding wire is to maintain the sheet in the rolled-up configuration until it is to be radially enlarged at a chosen placement site.

It is contended in the present action (page 3) that holding wire 8, because it is a wire, is "inherently radiopaque." Even if this contention is assumed correct arguendo, the Sigwart reference still fails to disclose the system of claim 35.

For example, the marker in claim 35, when removably attached to the endoprosthesis, improves the radiopacity of the endoprosthesis. As is readily apparent from the formula and explanation on page 4 of the present specification, a marker capable of improving the radiopacity of an endoprosthesis must have a higher level of radiopacity as compared to the endoprosthesis. The required high level is achieved through forming the marker, at least over its radiopaque portion, of a material having a higher radiopacity (i.e. a higher linear attenuation coefficient) than the material of the endoprosthesis. Alternatively, the marker may be more radiopaque by virtue of a greater size, especially thickness, as compared to the strands or filaments of the endoprosthesis.

Neither of these alternatives is taught by Sigwart. As for relative radiopacity, Sigwart teaches no distinction between its stent and its holding wire. Sigwart does not require that the wire be metal, much less have any particular level of radiopacity. The stent material is said to be malleable, and stainless steel is disclosed as a stent material. Assuming the holding wire is metal, there is no indication that such metal is more radiopaque than the stainless steel or other material of the rolled-up sheet.

Finally, in the context of Sigwart, where the stent or sheet is rolled into a spiral having multiple layers, such stent for purposes of radiopacity resembles a solid object of similar size. Thus, if Sigwart's holding wire is to improve the stent radiopacity, it must have a considerably higher level of radiopacity to make up for its small relative thickness.

As seen from Figure 1a in Sigwart, the holding wire is small in diameter (thickness), even as compared to the rolled-up stent. Thus, there is no teaching in Sigwart of a "marker" that improves endoprosthesis radiopacity by virtue of its thickness.

Finally, Sigwart mentions that the stent might be "formed of all kinds of materials such as metals and synthetic and ceramic materials" (column 4, lines 48-49). This, however, merely presents the possibility that someone skilled in the art, whether through experimentation or pure luck, might select different materials for the rolled-up sheet and holding wire to yield the desired result. Sigwart clearly provides no motive for the skilled person to proceed in that direction, since it does not even discuss fluoroscopic imaging.

Accordingly, Sigwart fails to anticipate the system of claim 35.

Claims 36-38, 44-45, 47-48, and 65 depend on claim 35 and are patentable for the reasons given in support of claim 35.

Claims 44 and 65 are patentable, further, for the failure of Sigwart to teach or suggest a marker that is attached to a delivery device, whereby withdrawal of the delivery device after it delivers the endoprosthesis removes the marker from the endoprosthesis. The present action (page 3) includes a contention that the Sigwart system includes a tubular delivery device "that removes the marker when withdrawn."

This contention is respectfully traversed. Figure 1a in Sigwart does not show holding wire 8 as attached to catheter 7, nor is such attachment mentioned anywhere in the text. Further, as noted above, Sigwart teaches that angioplasty balloon 6 is not inflated (to expand the stent) until after the holding wire is removed. The catheter cannot be used to enlarge the stent until the holding wire has been removed. Thus, the holding wire must be removed before the catheter can be withdrawn.

Claim 48 is patentable, further, for the failure of Sigwart to teach or suggest a wire for removably attaching the marker to the endoprosthesis.

The only wire disclosed in Sigwart is the holding wire 8, which the examiner has proposed as equivalent to the claimed marker. Claim 48 defines the wire as a separate element in addition to the marker, and there is no such element or equivalent in Sigwart.

Claim 53 has been amended to define the radiopaque portion of the strand as improving the radiopacity of the endoprosthesis when the strand is attached to the endoprosthesis, and further in that a segment of the strand comprises a component to facilitate pulling the strand.

The component is selected from the group consisting of: hooks, knobs, rings, eyelets, and handles.

Thus, claim 53, like claim 35, is distinguishable over Sigwart in providing that the marker improves the radiopacity of an endoprosthesis. Further, there is no teaching in Sigwart of the claimed component of the elongate strand that facilitates pulling the strand.

Accordingly, the marker of claim 53 is patentable over the Sigwart reference.

Claim 56 has been amended to incorporate attaching the marker to the implantable endoprosthesis to improve a radiopacity of the endoprosthesis, and in a manner that facilitates removal of the marker from the endoprosthesis when the endoprosthesis is *in vivo* after deployment.

Accordingly, claim 56 provides that the marker, at least its radiopaque portion, improves the radiopacity of the endoprosthesis. Further, the marker is mounted in a manner that facilitates its removal from the endoprosthesis after deployment. As noted previously, the holding wire in Sigwart must be removed before the stent can be radially enlarged into contact with tissue at the intended placement site. In other words, Sigwart's holding wire must be removed before deployment.

Claims 57-60 and 68 depend on claim 56, and are patentable for the reasons given in support of claim 56.

Claims 60 and 68 are patentable, further, for the failure of Sigwart to teach or suggest attaching the marker to the delivery device to enable removal of the marker by withdrawing the delivery device.

B. Claims 39-41, 51, 53-55, 64, 67 and 71-75 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,443,500 (Sigwart) in view of U.S. Patent No. 5,474,563 (Myler, et al.).

The Myler patent discloses a stent and retrieval apparatus. The stent is equipped with several inwardly directed hook-like projections 26 near its opposite ends. A retrieval catheter includes two rings or halos 62 and 66 that encounter the projections to facilitate retrieval of the stent. If desired, the halos can be formed of a radiopaque material.

There is no disclosure in Myler of the radiopacity of halos 62 and 66 as compared to the radiopacity of stent 10, and thus no indication of whether engaging the halos with the stent projections "improves" the stent's radiopacity. Moreover, because the halos are part of a stent retrieval or extraction tool, the suggestion to those of skilled in the art is that if fluoroscopic imaging is to be used, the stent should be as radiopaque as the halos - since the halos must be guided into congruence with the implanted stent.

Accordingly, claim 35 is patentable over the Sigwart/Myler combination, and claims 39-41, 51 and 64 are patentable by virtue of their dependency on claim 35.

Claim 39 is patentable, further, for the failure of the Sigwart/Myler combination to teach or suggest the claimed components (hooks, knobs, rings, or eyelets) at the free end of the marker. The only comparable structures are the hook-like projections in Myler. These projections, however, are permanently mounted to the stent, not to a radiopaque marker.

Claim 64 is patentable, further, for the failure of the Sigwart/Myler combination to teach or suggest attachment of the marker to a delivery device. Myler teaches nothing to compensate for the shortcomings of Sigwart in this regard. The only components equivalent to "markers" in Myler, i.e. the halos, are attached to an extraction device.

Claim 53 is patentable over the Sigwart/Myler combination by virtue of the feature that the radiopaque portion of the marker improves the radiopacity of the endoprosthesis. Also, with respect to the component of the strand segment that facilitates pulling the strand (e.g. a hook, knob, ring, eyelet, or handle), there is nothing in the Myler patent to compensate for the failure of Sigwart to disclose this feature.

Accordingly, the marker of claim 53 is patentable over the Sigwart/Myler combination.

Claims 71-75 depend on claim 53 and are patentable for the reasons given in support of claim 53.

With regard to claim 56, Myler discloses nothing to compensate for the failure of Sigwart to teach the claimed process. Accordingly, claim 56 is patentable over the Sigwart/Myler combination. Claim 67 is patentable by virtue of its dependency on claim 56.

To summarize, it is submitted that claims 35-53, 56-60, 64-68 and 71-79 in view of the present amendment, and new claims 80-86, incorporate subject matter patentable over the prior art of record. An early and favorable action allowing these claims is respectfully requested.

Respectfully submitted,

Boston Scientific Scimed, Inc.

Dated: June 10, 2004

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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment in Application Serial No. 10/008,716 is being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Dated: June 10, 2004

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Geralyn M. Vita

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